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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/292,758	04/14/1999	GLENN A. BURMER	017473-00111	4011

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/292,758

Applicant(s)

BURMER ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-11,29,31-33,38,55 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10,29,31-33,38,55 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634, and has been assigned to Primary Examiner Bradley L. Sisson.

Continued Prosecution Application

2. The request filed on 01 April 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/292,758 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restrictions

3. In the Office action of 05 May 2000-, a restriction was placed against the claims. The claims were divided into several groups, with Group I being drawn to those claims directed to nucleic acids and claims of Group II were directed to isolated polypeptide. Claim 11 was inadvertently included in Group I as it is clearly directed to the invention of Group II. Accordingly, claim 11 has been withdrawn for consideration as being drawn to an invention non-elected with traverse in Paper No. 9, received 01 June 2000.

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Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is noted that none of the elected claims are drawn to proteins.

5. Claims 29, 32, 38, 55, and 62 objected to because of the following informalities: The claims are all drawn to kits that comprise the same components and therefore are essentially duplicative. It is noted with particularity that the intended use of the components of the kits does not carry patentable weight nor further limit the components. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3 and 6-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As presently worded, claims 1-3 and 6-10 are generic in scope in that they a virtually limitless number of nucleic acid sequences. In comparison, the specification sets forth but two corresponding nucleotide sequences; SEQ ID NO: 1 and 2. The specification does not reasonably suggest that applicant was in possession of the genera of nucleotide sequences claimed at the time of filing, much less at the date upon which their priority document was filed. While one may asserts that it would have been obvious to one of skill in the

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art to identify and make these alternative embodiments, such an argument is not dispositive of a rejection based upon the written description requirement portion of 35 USC 112, first paragraph.

In support of this position, attention is directed to *University of California v. Eli Lilly and Co.*

(Fed. Cir. 1997) 43 USPQ2d at 1405:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Acknowledgement is made that the nucleic acid of claim 7 is defined in terms of it hybridizing to other nucleic acid sequences. The ability of one nucleic acid to hybridize to another, or to encode a polypeptide, are all considered to represent means by which the nucleic acid is being defined in terms of how it is to function, not in terms of what it is.

Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to provide an adequate written description of the claimed genera of nucleic acid sequences.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 29, 31, 38, 55, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson in view of Hillier et al. (Accession No. N53466).

12. Claims 29, 33, 38, 55, and 62 have been interpreted as encompassing not only the entire length of sequences represented by SEQ ID NOs, but also, portions thereof. Support for this interpretation is found in the specification at page 7 where it defines the terms so as to encompass polynucleotides that have "at least about 10 nucleotides."

13. Thompson, column 3, bridging to column 4, discloses kits comprising probes as well as labeled nucleic acid probe.

14. Thompson does not disclose the claimed sequences.

15. Hillier et al. (Accession No. N53466) disclose applicant's SEQ ID NO: 55. A said sequence is described as being a human EST.
16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed the human EST sequence, or portion thereof, into the kit of Thompson so to permit further evaluation of the EST as identification of EST sequences, and the human genome project in general, has been the focus of intense interest in the scientific community for several years.
17. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson and Hillier et al. (Accession No. N53466) as applied to claims 29-31, 38, 39, 55, and 62 above, and further in view of Sosnowski et al.
18. See above for the basis of the rejection as it relates to the disclosures of Thompson and Hillier et al.
19. Neither Thompson nor Hillier discloses a chip of sequences.
20. Sosnowski et al., disclose a chip that comprises an array of sequences and that the sequences can be from about 10 bases in length or longer (column 32). The wide applicability of such a device is seen at column 29, et al.
21. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in a kit a chip that presented immobilized nucleic acid sequences that, either with additional sequences such as that of Hillier et al., or separately, could be used in a variety of hybridization assays.
22. In view of the well developed nature of the art, the explicit teachings of how such chips could be synthesized, the explicit teachings of human EST sequences, and the profound interest

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in the art, the ordinary artisan would have been both highly motivated to have devised such a kit as well as have had a reasonably expectation of success in its production and utilization.

Response to arguments

23. At page 7 of the response received 01 April 2002 argument is advanced that the prior art does not describe the functional attributes of the claimed polynucleotide probes and as such, does not teach each and every limitation of the claim and therefore, the rejection should be withdrawn.

24. The above argument has been fully considered and has not been found to be persuasive towards the withdrawal of the rejection for while the prior art may not have recognized certain functional attributes of the claimed nucleic acids, the discovery of new properties of an otherwise old compound does not make the old compound now patentable. It may, however, be grounds for asserting non-obviousness for a new method of using the polynucleotide.

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
May 20, 2002